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09/177,814	10/23/1998	TERRY L. GILTON	353OUS(97-12	3621

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EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
1641	22

DATE MAILED: 07/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)
	09/177,814	GILTON, TERRY L.
	Examiner	Art Unit
	Gailene R. Gabel	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 April 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,3-11,13-44,46,48-64,66-74 and 105-107 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,3-11,13-44,46,48-64,66-74 and 105-107 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

Applicant's Response

1. Applicant's response filed 4/23/02 in Paper No. 21 is acknowledged. Currently, claims 1, 3-11, 13-44, 46, 48-64, 66-74 and 105-107 are pending and are under examination.

Rejections Maintained

Claim Rejections - 35 USC § 103

2. Claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) for reason of record.

3. Claims 8, 26-28, 35-37, and 66-68 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73 above, in further view of Swedberg et al. (US 5,571,410) for reason of record.

4. Claims 14-15, 17, 21, 40-41, 44, and 54-55 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73 above, and further in view of Miura et al. (US 5,132,012) for reason of record.

5. Claims 21 and 41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73 above, and further in view of Wang et al. (US 5,663,488) for reason of record.

6. Claims 22-24, and 42 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73 above, and further in view of Northrup et al. (US 5,882,496) for reason of record.

7. Claims 6, 57-62, and 72 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73, in further view of Northrup et al. (US 5,882,496) and Sunzeri (US 5,536,382) for reason of record.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 105-107 are rejected under 35 U.S.C. 102(e) as being anticipated by Thakur (US 6,225,159).

Thakur discloses an ultrasmall flow channel device (trench capacitor) comprising a flow inlet and a flow channel (elongate trench) formed on a surface of a semiconductor substrate which comprises silicon matrix and wherein a selected layer of the amorphous silicon is converted to hemispherical grained silicon (HSG) (see claim 33, column 6, lines 33-62 and column 7, lines 17-30).

9. Claims 105-107 are rejected under 35 U.S.C. 102(e) as being anticipated by Thakur et al. (US 6,126,847).

Thakur et al. disclose ultrasmall flow channels formed in semiconductor devices comprising a flow inlet and a flow channel (elongate trench) on a surface of the substrate which includes silicon oxide and wherein HSG is selectively etched and formed thereon (see column 3, line 57 to column 4, line 34, Figure 3, and column 5, lines 27-43).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 33, 63, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaka et al. (US 5,482,598) in view of Overton et al. (US 5,611,846) as applied to claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73 above, further in view of Northrup et al. (US 5,882,496), and in further view of Crenshaw et al. (US 5,726,085).

Isaka et al. and Overton et al. have been discussed in Paper No. 16. Isaka et al. and Overton et al. differ from the instant invention in failing to teach that the porous silicon matrix comprises hemispherical grained silicon (HSG).

To reiterate, Northrup et al. disclose fabrication and use of porous silicon structures to increase surface area of miniaturized electrophoresis devices and filtering or control flow devices (see Abstract). Northrup et al. specifically disclose that porous silicon which is fabricated from crystalline silicon have very small pore diameters so that they can be produced with relatively high degree of uniformity and control (see column 1, lines 27-55). Northrup et al. teach that because of its high surface area and specific pore size, porous silicon can be utilized for a variety of applications on a miniature scale for significantly augmenting adsorption, vaporization, desorption, condensation, and flow of liquids and gasses while maintaining the capability of modification such as being

doped or coated using conventional integrated circuit and micromachining (see Summary).

Crenshaw et al. disclose a capacitor wherein a thin layer of HSG is deposited over a doped polysilicon region and then etched using etch chemistry, to increase surface area (see column 1, lines 51-65, column 3, and Figure 4C).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the porous silicon matrix disclosed by Isaka or Northrup as modified by Overton, with HSG as taught by Crenshaw because Crenshaw taught using HSG on capacitors to increase surface area and Northrup specifically taught that porosity in silicon structures increases surface area in miniaturized separation flow channels such as in his electrophoresis device or the microchannel separation device disclosed by Isaka and HSG appears to constitute an obvious variation of porous silicon used in separation devices. Further, both devices taught by Isaka and Northrup appear to be generic with respect to the type of porous silicon used in their microchannel devices.

Response to Arguments

11. Applicant's arguments filed 4/23/02 have been fully considered but they are not persuasive.

A) Applicant argues that one of ordinary skill would not have been motivated to combine the teachings of Isaka with that of Overton because Isaka does not teach or suggest the desirability of multiple porous silicon columns and Overton does not teach

or suggest the desirability of multiple columns on chromatograph devices comprising porous silicon such as taught by Isaka. Applicant, therefore, contends that the Office relied on Applicant's disclosure or "unarticulated general knowledge" in the art in teaching the conclusion that the cited references should be selected and proposed which are improper bases for an obviousness rejection.

In response, the rejection of claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 25, 29-32, 34, 38-39, 43, 46, 48-53, 56, 64, 69-71, and 73 is based on an obvious combination of the teachings of Isaka and Overton. Specifically, Isaka was cited as a primary reference for his teaching of a column chromatograph that includes a single porous silicon column. It is noted that a teaching or desirability of multiple columns in the porous silicon substrate of Isaka would have, otherwise, warranted an anticipatory rejection to the claims. Overton was cited as a secondary reference for his teaching of multiple column configurations in miniaturized column chromatographs. It is, likewise, noted that a teaching or desirability of multiple columns incorporated specifically into porous silicon substrate in the Overton reference would have, otherwise, warranted an anticipatory rejection to the claims. In further response to Applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Isaka specifically discloses a chromatograph that includes a silicon substrate having formed thereto a single porous microchannel, as opposed to two porous microchannels. Overton was merely cited for his teaching of a miniaturized portable gas chromatograph having multiple columns. One of ordinary skill in the art at the time of the instant invention would have had reasonable expectation of success in incorporating multiple columns into the miniaturized porous silicon device of Isaka because Overton specifically showed that multiple columns can be fabricated in miniaturized chromatographic devices. Further, it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.* 193 USPQ 8.

B) Applicant argues that the open channel, porous material-filled substrate bound column of Swedberg does not cure the deficiencies of Isaka and Overton. Applicant contends that Swedberg does not provide any suggestion or motivation to combine the single porous column of Isaka with the multiple interconnected columns of Overton to produce the claimed invention.

In response, Swedberg was combined with the teaching of Isaka and Overton for the teaching of a capture function that can be incorporated into miniaturized chromatographic devices wherein antibodies, antigens, and other biological affiants are immobilized into the column matrix for capturing biological components and separating them from other components in the sample. Further, although the Swedberg reference was not depended upon, as a secondary reference for the teaching of multiple

microchannels, it is noted at column 10 of the Swedberg reference that complementary microchannels (more than one channel) can be fabricated with enhanced alignment capability with the use of laser ablation techniques. Therefore, contrary to Applicant's argument, Swedberg, does provide a suggestion to fabricate multiple microchannels in a chromatographic device, if desired.

C) Applicant argues that one of ordinary skill would not have been motivated to combine the teachings of Isaka and Overton with Miura and that there is no reasonable expectation of success in so doing. Applicant argues that Isaka, Overton, and Muira fail to teach a memory device on the substrate, a vacuum source in operative communication with a porous region, and that Miura only teaches use of positive pressure to facilitate movement of a sample.

In response, Overton and Miura each include a memory device but not specifically disposed on the substrate. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to dispose the memory device taught by Overton and Miura into the substrate because it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. Also, it has been held that forming in one piece an article which has formerly been formed in two separate pieces and put together, i.e. memory device [disposed] on the substrate, involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893)).

In addition, Miura, indeed, teaches a migration facilitator comprising a pump that is fed under positive pressure into the feed pump to facilitate movement of the sample (column 4, lines 4-59). Further, Applicant, by way of disclosure at page 14, lines 9-10 in the specification admits that migration facilitators may alternatively comprise a vacuum source well known in the art which exerts a negative pressure in order to pull a sample along a capillary column.

D) Applicant argues that one of ordinary skill would not have been motivated to combine the teachings of Isaka and Overton with Wang and that there is no reasonable expectation of success in so doing. Applicant argues that Isaka, Overton, and Wang fail to teach a vacuum source that is operatively in communication with an end of the chromatography column. According to Applicant, the vacuum source of Wang is “used to vary the pressure within a chamber in which the column has placed” but “the vacuum source is not in operative communication with the column”.

In response, Wang was incorporated with the teachings of both Isaka and Overton for his disclosure of a migration facilitator comprising exemplary pumps to facilitate migration of the samples through the claimed column. Further, Applicant, by way of disclosure at page 14, lines 9-10 in the specification admits that migration facilitators may alternatively comprise a vacuum source known in the art which exerts a negative pressure in order to pull a sample along a capillary column.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically

pointing out how the language of the claims patentably distinguishes them from the references. Specifically, the recitation of "in operative communication with the column" does not exclude "varying the pressure within a chamber in which the column has been placed".

E) Applicant argues that the multiple disconnected, substrate-bound porous columns of Northrup do not cure the deficiencies of Isaka and Overton. Applicant contends that Northrup does not provide any suggestion or motivation to combine the single porous column of Isaka with the multiple interconnected columns of Overton to produce the claimed invention.

In response, Northrup was combined with the teaching of Isaka and Overton for the teaching of electrodes within or adjacent porous membranes which are used to control flow of electrically charge biochemical species such as in electrophoresis, i.e. negative electrode is formed at one end (inlet) of a column and a positive electrode is formed is formed at an opposite end of a column, thereby forming microelectrophoresis channels. Further, although the Northrup reference was not depended upon, as a secondary reference for the teaching of multiple microchannels, it is noted that the Northrup reference exemplifies multiple microelectrophoresis channels (more than one channel) in his device. Therefore, contrary to Applicant's argument, Northrup, does provide a suggestion to fabricate multiple microchannels in a chromatographic device, if desired.

F) Applicant argues that neither the multiple disconnected, substrate-bound porous columns of Northrup nor the electrophoretic-media filled capillary tubes used in Sunzeri, cures the deficiencies of Isaka and Overton. Applicant contends that Northrup and Sunzeri do not provide any suggestion or motivation to combine the single porous column of Isaka with the multiple interconnected columns of Overton to produce the claimed invention.

In response, Northrup was combined with the teaching of Isaka and Overton for the teaching of electrodes within or adjacent porous membranes which are used to control flow of electrically charge biochemical species such as in electrophoresis, i.e. negative electrode is formed at one end (inlet) of a column and a positive electrode is formed is formed at an opposite end of a column, thereby forming microelectrophoresis channels. Sunzeri was further combined thereafter for the teaching of incorporating internal or external standards into a column chromatographs. One of ordinary skill in the art would have reasonable expectation of success in incorporating internal controls as suggested by Sunzeri, upon the miniaturized chromatographic devices taught by Isaka and Overton as modified by Northrup, because internal controls in a chromatography device for quality control monitoring, is conventional and standard laboratory practice to those well within ordinary skill. Further, although the Northrup reference was not depended upon, as a secondary reference for the teaching of multiple microchannels, it is noted that the Northrup reference exemplifies multiple microelectrophoresis channels (more than one channel) in his device. Therefore,

contrary to Applicant's argument, Northrup, does provides a suggestion to fabricate multiple microchannels in a chromatographic device, if desired.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel
Patent Examiner
Art Unit 1641


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07/05/02